



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Howard A. Kingsford
Serial No. : 09/440,384
Filed : November 15, 1999
Title : SKIN ATTACHMENT MEMBER

Art Unit : 1772
Examiner : Marc A. Patterson

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

Velcro Industries B.V.

(2) Related Appeals and Interferences

There are no related Appeals or Interferences.

(3) Status of Claims

Claims 2-23 are pending and under examination. All of the claims are rejected under either 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a).

(4) Status of Amendments

All amendments have been entered. No amendments are being made herewith.

(5) Summary of Claimed Subject Matter

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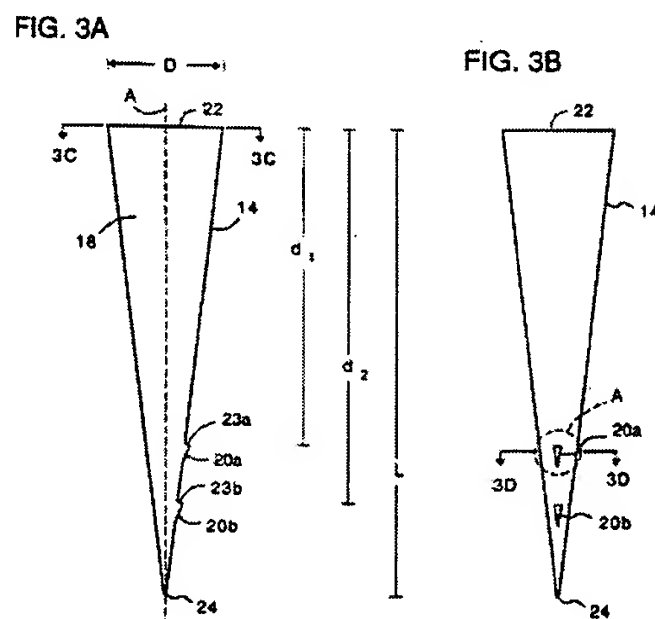
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The pending claims all recite a skin attachment member of plastic resin. The skin attachment member includes a backing, and an array of skin penetrating elements extending integrally from a surrounding surface of the backing to a tip. The skin penetrating elements are sized to avoid contact with nerves below the epidermal skin layer. A plurality of the skin penetrating elements each include a retention barb extending from an outer surface of the skin penetrating element, and the array of skin penetrating elements, including each retention barb, is formed integrally from a single plastic resin.

In an illustrated embodiment shown in Figs. 3A and 3B, the skin penetrating elements have a cone shaped body with one or more discrete barbs extending from the body to secure the skin attachment member to the epidermis. The cone shape body generally tapers from a larger diameter proximal base to a distal pointed tip. The discrete barbs are located on the cone shaped body to take advantage of the greater elasticity of the skin portions lying below the stratum corneum to provide greater holding force.



(6) Grounds of Rejection

Claims 4, 10, 16-17, 19-21 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,312,456 to Reed et al. ("Reed")¹. Claims 2-3, 5-9, 11-12 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed.² Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed in view of U.S. Patent No. 5,031,609 to Fye ("Fye"). And, claims 14-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed in view of U.S. Patent No. 4,219,019 to Coates ("Coates").

¹ While the Examiner lists claims 4, 10, 16-17, 19-21 and 23 as being repeated rejections over Reed, the previous Office Action, dated April 30, 2004, rejected claims 2-12 and 16-23 over Reed. Because the Examiner has not indicated any of the claims are allowable, Applicant assumes that the rejection over all of claims 2-12 and 16-23 is maintained.

² While the Examiner does not expressly include claim 22 in this rejection, the Examiner in the previous Office Action, dated April 30, 2004 included claim 22 in the discussion of this rejection. Because the Examiner has not indicated a withdrawal of any of the previous rejections, Applicant assumes this rejection is maintained.

(7) Argument

Anticipation by Reed

Reed discloses a member having “micromechanical barbs,” 16 each having a head 20 disposed upon a support 18 extending from a base 22. The head has extremity portions 26 for interlocking with other barbs or forming a locking connection with another object.³ The head may have a pointed central portion 24, for piercing skin, for example.⁴

Regarding materials, Reed says of his skin penetrating elements that:

The base 22, head 20 and support 18 are made of a rigid material. The rigid material can be, for instance, metal, ceramic, plastic, composite material or alloy. The metal could be steel, the ceramic could be aluminum oxide, the composite material could be graphite fiber matrix composite and the plastic polysulfone. Preferably, the base and support are made out of Si and the head is made out of SiO₂.⁵

As seen in the above quoted passage, the elements in Reed preferably include a head made out of a first material (i.e., silicon dioxide) and a base and support made of a second, different material (i.e., silicon). The Examiner cites the above passage to support his finding that Reed “discloses a penetrating element formed from a single plastic resin,” especially the sentence stating that the base, head, and support are made of “a rigid material.”⁶

Reed's sole disclosed method of making the “micromechanical barbs” is by a photochemical etching process in which layers of different materials are sequentially etched to

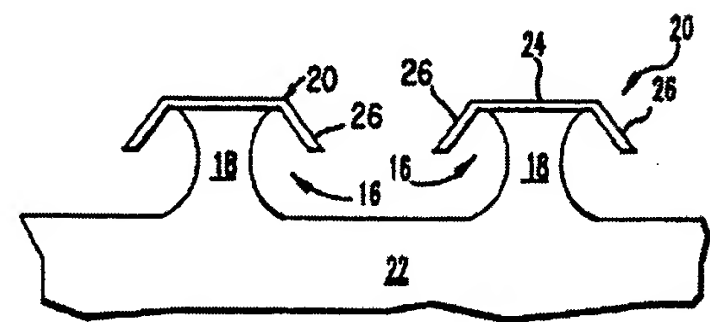


FIG. 2

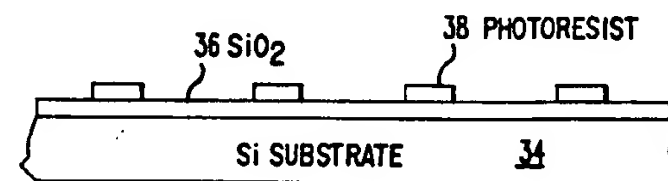


FIG. 9a

³ See Reed et al. at col. 3, lines 35-39.

⁴ Id., col. 4, lines 28-32.

⁵ See Reed, Col. 3, lines 39-36.

⁶ See Office Action of April 30, 2004, p. 3.

leave "barbs" of the desired shape.⁷ To begin, a substrate 34 (such as Si or steel) is provided with a layer 36 of a *second* material, such as SiO₂, thereon, and at predetermined discrete locations 28 on the layer 36 a third material, such as a photoresist as shown in FIG. 9a. Portions of the layer 36 and the substrate 34, but not the third material, are then removed such that a frustrum shape is formed on the surface of the substrate 34, as shown in FIG. 9b. The third material is then removed, leaving the first and second materials essentially untouched as shown in FIG. 9b. Then layer 36 is reformed, as shown in FIG. 9c, followed by removing portions of the layer 36 at essentially the center of the lowest points of the frustrum of the layer 38. Finally, portions of the substrate 34 are removed by an etchant applied over the entire surface of the substrate. Because of the differences in etch susceptibility between layers and 36, layer 36 remains, whereas underlayer 34 is etched beneath, creating a plurality of barbs 16 as shown in FIG. 9d.⁸

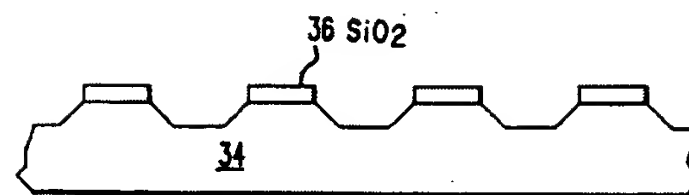


FIG.9b

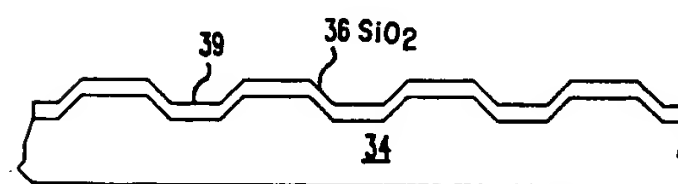


FIG.9c

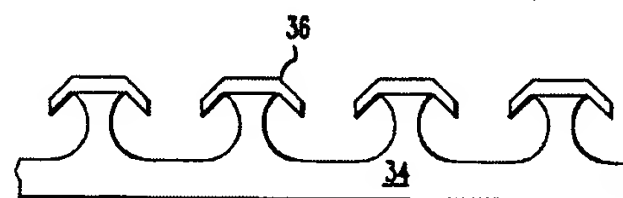


FIG.9d

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"To be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure."⁹ In other words, the reference must enable an embodiment of the claimed invention. Reed does not enable one of ordinary skill in the art to make any skin penetrating elements as recited in the pending claims. Instead, as described above, the only method Reed discloses to make "micromechanical barbs" is by a photochemical etching process in which layers of different materials are

⁷ See Reed et al. at col. 5, lines 39-59 and col. 6, lines 40-60.

⁸ Id., col. 5, lines 39-59, emphasis added.

⁹ See Chester v. Miller, 906 F.2d 1574 (Fed. Cir. 1990). (Emphasis added.)

sequentially etched to leave “barbs” of the desired shape, each barb necessarily comprised of two materials of differing etch susceptibility.¹⁰

While unclear from the Office Action, the Examiner may be basing his rejection in part on improperly concluding that the phrase “formed integrally of a single plastic resin” is a process limitation, thereby making the claim a product by process claim in which the process limitation need not be accorded weight. However, the limitation requiring the penetrating elements to be “formed integrally of a single plastic resin” recites a structural characteristic of the claimed product and therefore is entitled to full weight and consideration in examination in the context of a product claim. Accordingly, Reed does not anticipate Applicant's claims at least because Reed does not disclose, and does not enable the formation of, penetrating elements of such a structure.

Applicant previously presented evidence supporting his assertion that Reed does not anticipate the pending claims, in the form of a Declaration under 37 C.F.R. §1.132 (“the Harvey Declaration”). In his declaration, Mr. Harvey states that the barbs 16 disclosed in Reed are made from a process referred to as “undercut etching.” This is accomplished in Reed by providing a multi-layered base substrate where portions of an overlying layer are removed to expose corresponding portions of the underlying layer 34. The exposed portions of the underlying layer are then partially etched away by “lateral undercutting” to leave the remaining portions of the overlying layer centrally supported by the remaining portion of the underlying layer. To achieve the “lateral undercutting” so that the extremity portions 26 that overhang the base formed by the underlying layer 34, *“it is important that the underlying layer 34 be more susceptible to the applied etchant than the overlying layer 36 in this final step.”* (Emphasis added) Accordingly, in the sole example provided by Reed, the underlying layer is made of silicon (Si) and the overlying layer is made of silicon dioxide (SiO₂). Mr. Harvey then concludes that Reed “in no way teaches or suggests a technique for manufacturing a barb in which the base 22, head 20, including central 24 and extremity portions 26, and support 18 are all formed *integrally of a single plastic resin.*”

While Reed does include a statement that, “(t)he base 22, head 20 and support 18 are made of a rigid material.” One of ordinary skill in the art, when viewing Reed as a whole, would

¹⁰ See Reed Col. 5, lines 39-59, Col. 6, lines 40-60, and Figs. 9a-9d.

not understand Reed to have disclosed skin penetrating elements formed integrally of a single material. Instead, taking the above quote in context of the entire disclosure, one of ordinary skill in the art would understand Reed to mean that each of the base, head, and support are made from a rigid material, but not of the same rigid material. Stated differently, a fair reading of Reed requires the head to be formed of a first material and the body to be formed of a second, different material.

Moreover, evidence traversing rejections, when timely presented, must be considered by the examiner. (See M.P.E.P. §716.01.) In this instance, the Examiner does not even comment on the Applicant's evidence as presented in the Harvey declaration, but instead dismisses this evidence out of hand. Such a dismissal is improper, and Applicant requests that the presented declaration be given the weight and consideration deserved by one of such skill in the art.

Obviousness over Reed

Even a conclusion of obviousness requires that the cited reference or combination of references relied upon be so enabling as to place the public in possession at least an embodiment of the claimed invention.¹¹ The Examiner's obviousness rejections are all derived from the incorrect assertion discussed above, that Reed fairly discloses and enables claim 19. Nevertheless, each of these rejections is addressed in turn below.

Regarding the claims rejected over Reed as a single reference, Applicant has already shown that Reed does not enable the claimed invention, and therefore the single-reference §103 rejections over Reed should also be withdrawn. Moreover, in addition to Reed's lack of enabling disclosure, nothing in Reed would suggest the skin attachment member of the structure recited in the pending claims.

Furthermore, none of the suggested combinations of references with Reed to reject claims under 35 U.S.C. §103 enable the claimed invention, as none of the secondary references provide any insight into how one of ordinary skill in the art could have produced a skin attachment member of the structure claimed. Therefore Applicant respectfully submits that the Examiner

¹¹ See Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 13 USPQ2d 1301 (Fed. Cir. 1989) ("In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method."), In re Epstein, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (The references "must be enabling, thus placing the alleged disclosed matter in the possession of the public."), and In re Hoeksema, 399 F.2d 269, 274 (CCPA 1968)

has not produced a *prima facie* case of obviousness of the claims rejected over combinations of references, and asks that these rejections also be withdrawn.

With regard to claims 2, 3, and 22, Applicant disagrees with the Examiner's broad assertion, citing In re Dailey, that a recited limitation directed to a change in shape is generally obvious to one of ordinary skill in the art.¹² The real issue is whether the claimed limitation is novel and non-obvious over the prior art. The Applicants in In re Dailey lost their case by not being able to show that the 'less than hemispherical' shape of their design was in any way "significant."¹³ Applicant here, on the other hand, has explained the significance of the recited shape with respect to skin penetration and retention, as well as limiting the detrimental effect to the skin due to the penetration.¹⁴

Similarly, with regard to claims 5-9, 11, 12 and 18, the Examiner states that Reed fails to disclose the respective limitations, but that one of ordinary skill in the art would recognize the advantage of varying the diameter, length and angle of point of the penetrating element, the thickness of the backing and number of elements per area to obtain a desired range of flexibility.¹⁵ While Applicant submits that these claims are allowable at least as depending from an allowable base claim 19, for the record Applicant traverses the legitimacy of this rejection as being unsubstantiated by the prior art of record. There is simply no evidence presented for the conclusion that all of these parameters are merely matters of 'routine optimization' or design choice, or are even all related to flexibility, as advanced by the Examiner.

Regarding claims 13, 14 and 15, Fye and Coates disclose bandages of various materials (e.g., nylon and polyethylene teraphthatlate, respectively). However, neither reference

¹² In re Dailey was a simple affirmation by the CCPA in 1966 of a board decision that the particular configuration of a disposable nursing container was "not significantly novel" over the prior art, and notably contained no broad statement concerning the obviousness of changes in shape. The only relevant statement by the court was that the Dailey had "presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious..." (In re Dailey, 357 F.2d 669 at 672). It is regrettable that such a case is characterized by the MPEP as standing for such a proposition, and that few Examiners read the case.

¹³ See In re Dailey, 357 F.2d 669 (CCPA 1966).

¹⁴ See Applicant's Specification, page 4, line 15, for example.

¹⁵ The Examiner refers to Reed, col. 4, lines 47-48 as teaching that maximum flexibility is desired, but this passage simply refers to the desirability of grooving an annulus secured inside a blood vessel, such that "when the blood vessel 63 is attached under pressure to the annulus 52, the annulus breaks apart along the grooves", as noted in lines 49-53. In any event, this is far from evidence of motivation to modify such things as the pointedness of the tip of the penetrating element, or the density of penetrating elements, for example.

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overcomes the above-described deficiencies of Reed as concerning claim 19, discussed above, and Applicant submits that these dependent claims are therefore also allowable over the cited references.

In view of the foregoing arguments and evidence supporting these arguments, Applicant submits that the pending claims are patentable and request that the Application be allowed.

The brief fee of \$500 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: March 16, 2005

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Appendix of Claims

2. The skin attachment member of claim 19 wherein each skin penetrating element comprises a cone-shaped body.

3. The skin attachment member of claim 2 wherein a base of the cone-shaped body has a diameter of about 0.003 inch (0.08 mm).

4. The skin attachment member of claim 19 wherein said tip of each skin penetrating element has a pointed shape.

5. The skin attachment member of claim 19 wherein each skin penetrating element has a length of about 0.012 inch (0.3 mm).

6. The skin attachment member of claim 19 wherein the backing has a thickness in a range of about 0.003 to 0.008 inch (0.08 to 0.2 mm).

7. The skin attachment member of claim 19 wherein the retention barb of each of said plurality of skin penetrating elements is located about 0.008 to 0.0095 inch (0.2 to 0.24 mm) along a length of the skin penetrating element from the backing.

8. The skin attachment member of claim 19 wherein the retention barb of each of said plurality of said skin penetrating elements has a length of about 0.0001 inch (0.003 mm).

9. The skin attachment member of claim 19 wherein the retention barb of each of said plurality of skin penetrating elements tapers from a thickness of about 0.0001 inch (0.0003 mm) to a point at an angle of about 72 degrees.

10. The skin attachment member of claim 19 wherein each of said plurality of skin penetrating elements includes two of said barbs.

11. The skin attachment member of claim 19 having a density of about 400 skin penetrating elements in a 0.1 inch^2 (65 mm^2) area.

12. The skin attachment member of claim 19 wherein the skin penetrating elements are spaced apart from each other a distance of about 0.003 inch (0.08 mm).

13. The skin attachment member of claim 19 formed from nylon.

14. The skin attachment member of claim 19 formed from polyethylene teraphthalate.

15. The skin attachment member of claim 19 formed from polyester.

16. The skin attachment member of claim 19 wherein the sheet-form backing and the skin penetrating elements, including each barb, are molded integrally of a single plastic resin.

17. The skin attachment member of claim 19 wherein a plurality of the skin penetrating elements each define a groove in said outer side surface.

18. The skin attachment member of claim 19 wherein the skin penetrating elements are oriented perpendicular to the backing.

19. A skin attachment member of plastic resin, comprising:

a backing, and

an array of skin penetrating elements extending integrally from a surrounding surface of the backing to a tip, the skin penetrating elements sized to avoid contact with nerves below the epidermal skin layer,

a plurality of the skin penetrating elements each including a retention barb extending from an outer surface of the skin penetrating element,

wherein the array of skin penetrating elements, including each retention barb, is formed

integrally from a single plastic resin.

20. The skin attachment member of claim 18 wherein each skin penetrating element intersects said sheet form backing to define a base and each skin penetrating element tapers continuously from said base to said tip.

21. The skin attachment member of claim 10 wherein said two barbs of each of said plurality of skin penetrating elements are disposed at different distances from said sheet-form backing.

22. The skin attachment member of claim 19 wherein said barb of each of said plurality of skin penetrating elements defines a half-pyramid shape.

23. The skin attachment member of claim 21 wherein said barb has a lower surface disposed substantially perpendicular to a central axis of the skin penetrating element from which it extends.